DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 18, 2015

Ms. Ronda K. Magneson
Director of Regulatory Affairs
Megadyne Medical Products, Incorporated
11506 South State Street
Draper, Utah 84020

Re: K141587
Trade/Device Name: Zip Pen Smoke Evacuation Electrosurgical Pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical, Cutting & Coagulation & Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 12, 2015
Received: January 14, 2015

Dear Ms. Magneson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141587

Device Name
ZIP PEN Smoke Evacuation Electrosurgical Pencil

Indications for Use *(Describe)*
The ZIP PEN Smoke Evacuation Pencil is a monopolar device designed for general electrosurgical applications including cutting and coagulation and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. This device conducts an electrosurgical current from an electrosurgical generator and delivers it to the target tissue to achieve the desired surgical effect

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

## I. SUBMITTER

Megadyne Medical Products, Inc.
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Contact Person (Alternate): Katie Hoff
Regulatory Affairs Specialist
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Date Prepared: February 18, 2015

## II. DEVICE

| | |
|---|---|
| Name of Device: | ZIP Pen Smoke Evacuation Electrosurgical Pencil (catalog numbers 2525-10 and 2525-15) |
| Common Name: | Smoke Evacuation Electrosurgical Pencil |
| Classification Name: | Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400) |
| Regulatory Class: | Class II |
| Product Code: | GEI |

## III. PREDICATE DEVICE

Telescoping PenEvac, K961616 cleared May 28, 1996

## IV. DEVICE DESCRIPTION

The ZIP Pen Smoke Evacuation Electrosurgical Pencil is a sterile, single use hand held electrosurgical pencil and smoke evacuation handpiece. It is a monopolar device designed for general electrosurgical applications including cutting and coagulation and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

The device consists of a printed circuit board, flexible electrical cable, dome switches, button switch mechanisms and sealing materials. The circuit board and electrical cable provide the means for powering the device. The dome switches operate the Cut and Coag functions. These components are enclosed within an upper housing and lower molded carriage and nozzle, which snap together. The buttons sit on top of the dome switches and extend through the upper housing and facilitate activation of the device. The button proximal to the electrode is yellow and controls the cut function of the device. The button distal to the electrode is blue and controls the coagulate function of the device. Within the nozzle, there is a metal collett that holds the electrode in place. The housing and other components are designed and assembled to prevent liquid from entering the electrical connections (preventing an electrical short). This is accomplished by over molding the circuit board with nonconductive materials.

Clear tubing connects to the nozzle and provides a path for capturing electrosurgical smoke. The electro-surgical cable leaves the tubing through an open port and terminates at a 3-prong electro-surgical plug. The remaining portion of the tubing (without cable inside) terminates at a connector that attaches to the smoke evacuation filter. The connector is attached to the tubing and is included as part of the smoke evacuation pencil for connection to the filter.

The ZIP Pen Smoke Evacuation Electrosurgical Pencil is available with 10 ft. and 15 ft. cord/tubing (catalog numbers 2525-10 and 2525-15, respectively) and is supplied with two additional items:

- A holster, which is used to hold the device when it is not in use during the procedure. The holster is a component of the device and will not be sold separately.
- A 2.5 inch Megadyne E-Z Clean electrode. The electrode is a separate, currently marketed device that received clearance in 2008 via K081791.

The associated accessories include:

- Nozzle Extension - can be used in electrosurgery procedures where a longer electrode is required to extend the smoke capture nozzle to the surgical site.
- Filter – the ULPA and charcoal filters can be used with smoke evacuation units. They filter surgical smoke and odors removed from the surgical site.
- Adapter - can be used to facilitate the tubing connection to a variety of smoke evacuation filter/units on the market.

## V. INDICATIONS FOR USE

The ZIP Pen Smoke Evacuation Electrosurgical Pencil is a monopolar device designed for general electrosurgical applications including cutting and coagulation and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The device conducts electrosurgical current from an electrosurgical generator and delivers it to the target tissue to achieve the desired surgical effect.

The indications for use for the subject device are fundamentally identical to that of the predicate device, and any minor variations in wording do not affect the safety and effectiveness of the device when used as labeled.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The ZIP Pen Smoke Evacuation Electrosurgical Pencil shares the same technological characteristics and is constructed of similar materials, chemical composition, and use the same energy source found in the predicate device. It is a handheld electrosurgical device used for cutting, coagulation and smoke removal during electrosurgical procedures. At a high level, the subject and predicate devices are based on the following same technological elements:

- Operation function switches – used to switch between "Cut" and "Coag"
- Electrode – monopolar
- Nozzle construction – polycarbonate
- Power supply – monopolar electrosurgical generator
- Electrical connector – US-3-pin
- Use of a smoke evacuation system
- Use of filters to filter surgical smoke removed from the surgical site.

## VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

### Sterilization

The ZIP Pen Smoke Evacuation Electrosurgical Pencil and the nozzle extensions are sterilized by exposure to radiation to a Sterility Assurance Level (SAL) of $10^{-6}$. Effectiveness of the sterilization cycle and sterilizing dose was qualified according to the requirements of *ANSI/AAMI/ISO 11137-2:2013, Sterilization of health care products –Radiation – Part 2: Establishing the sterilization dose.*

These devices have a shelf life of 3 years.

### Biocompatibility Testing

The biocompatibility testing for the ZIP Pen Smoke Evacuation Electrosurgical Pencil was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," May 1, 1995, and International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluating and Testing Within a Risk Management Process," as recognized by the FDA. The series of testing included the following tests:

- Cytotoxicity
- Intracutaneous reactivity (Irritation)
- Maximization sensitization (Sensitization)

The ZIP Pen Smoke Evacuation Electrosurgical Pencil fulfilled all requirements of the test protocol and the standard.

### Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the ZIP Pen Smoke Evacuation Electrosurgical Pencil. The system complies with the ANSI / AAMI / IEC 60601-1 and the ANSI / AAMI / IEC 60601-2-2 standards for safety and EMC.

### Software Verification and Validation Testing

Not applicable. The ZIP Pen Smoke Evacuation Electrosurgical Pencil does not contain software.

### Performance Testing - Bench

The ZIP Pen Smoke Evacuation Electrosurgical Pencil was exposed to performance bench testing to ensure conformance with the ANSI / AAMI / IEC 60601-1 and the ANSI / AAMI / IEC 60601-2-2 standards. The following tests were performed:

- High frequency dielectric withstand
- Mains frequency dielectric withstand
- Continuity
- Leakage current
- Fluid Ingress

### Animal Study

Not applicable. Animal studies were not performed on the device.

### Clinical Studies

Clinical studies were not performed as the indications for use are equivalent to the predicate device, and clinical testing is not required by applicable regulations.

## VIII. CONCLUSIONS

The ZIP Pen Smoke Evacuation Electrosurgical Pencil has the same intended purpose, indications and technological characteristics as the Telescoping PenEvac (K961616). The subject device also successfully passed all applicable performance and biocompatibility testing and is appropriate for its intended use.

The ZIP Pen Smoke Evacuation Electrosurgical Pencil does not raise different questions regarding safety and effectiveness as compared to predicate device. The ZIP Pen Smoke Evacuation Electrosurgical Pencil fulfills the relevant requirements of IEC 60601-2-2 and ISO 10993-1. Therefore, the subject device is as safe, as effective, and performs as well as or better than the predicate device, and is substantially equivalent to the predicate device.